

Wisconsin Department of Safety and Professional Services

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Website: <http://dsps.wi.gov>

PHARMACY EXAMINING BOARD

APPLICATION INFORMATION REGARDING LICENSURE OF A WHOLESALE DISTRIBUTOR

(NEW, CHANGE-IN-OWNERSHIP, OR CHANGE-OF-LOCATION)

A completed application must be on file with the Pharmacy Examining Board at least 30-days prior to opening. An application is not complete until all of the following are received:

1. **Complete Application for the Licensure of a Wholesale Distributor of Prescription Drugs (Form #2814):** To determine when a change of ownership occurs please view chart on page 3.
2. **Convictions and Pending Charges (Form #2252):** All applicants will be required to answer questions on the application form about convictions of any crime, other violations and pending charges in Wisconsin or any other state.

If an applicant has been convicted of one or more misdemeanor or other violations or has pending charges and if the Pharmacy Examining Board determines that the crimes or violations are substantially related to the practice of a wholesale distributor, the Board will not grant a license until it has received sufficient information to determine whether the license should be granted, denied or limited. It is the responsibility of the applicant to provide complete information to the Board. Applications are deemed complete after submission of all relevant background information by the applicant.
3. **Fingerprints:** You will receive information on how to obtain digital fingerprints *after* the Department has received a signed Authorization for Release of FBI Information (Form #2687).
4. **The Authorization for Release of FBI Information (Form # 2687):** must be signed by the applicant and returned with the application. This form must be submitted for Designated Representatives listed on the Wholesale Distributor Application Form (#2814).
5. **Complete and submit Designated Representative Form (#2812):** for the named designated representative listed on Application (Form #2814). This form must have a current photograph of head and shoulders of designated representative attached.
6. **Phar 13.05(4) Surety Bond (Form #2819), Irrevocable Letter of Credit (Form #2824): (DSPS forms must be used. There are no exceptions or modifications to the form that will be approved.)** All applicants shall supply a surety bond or irrevocable letter of credit in the amount of \$5,000.00, which is issued by a company authorized to do business in the State of Wisconsin. The form of the bond or letter of credit shall be approved by the department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a wholesale distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this subsection more than one year after the date on which the applicant's wholesale distributor's license expires. SURPLUS LINE – Insurers ARE NOT authorized to do surety business in Wisconsin.
 - a) **If the applicant chooses to obtain the \$5,000.00 surety bond, complete and return the Bond of Prescription Drug Wholesale Distribution (Form # 2819).**
 - b) **If the applicant chooses to submit a \$5,000.00 Irrevocable Letter of Credit, complete and return the Letter of Credit (Form #2824).**
7. **Forward the above items, along with the required fee, to the Pharmacy Examining Board at the address above, at least 30-days prior to the proposed opening date.** Requirements and procedures for applying for a wholesale distributor license are specified in Wis. State Stats. § 450.071. A license application and fee shall be on file with the Board at least 30-days prior to the granting of the distributor license. If you have not been inspected in the 3-year period immediately preceding the date of this application, your application will be denied and the application fee will not be returned. Once the required inspection is obtained, a new application will need to be filed and a new application fee paid. You may not conduct business in Wisconsin while awaiting licensure. A distributor may not operate unless a distributor license has been granted. Board action shall be taken within 60 business days of receipt of a completed distributor application, as provided in s. RL 4.03.

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8. **If controlled substances are distributed**, contact the Federal Drug Enforcement Administration for registration forms at www.deadiversion.usdoj.gov, (312) 353-1236, DEA, 230 South Dearborn Street, Ste. 1200, Chicago, Illinois 60604.

Procedure for Reporting Theft or Loss of Controlled Substances

The Designated Representative is responsible for reporting any theft or loss of controlled substances to the U.S. Department of Justice, DEA Kluczynski Building, Ste. 1200, 230 S. Dearborn Street, Chicago, IL 60604 (312-353-1236, or 1-800-478-7642 toll free 24 hours), and to the Pharmacy Examining Board, P.O. Box 8935, Madison, WI 53708-8935, (608-266-2112). Report the theft or loss on DEA Form #106 (Report of Theft or Loss of Controlled Substances), obtainable from DEA at www.deadiversion.usdoj.gov. Make four (4) copies. Send the original and one copy to the DEA office, one copy to the Pharmacy Examining Board, and one copy should be kept with the biennial inventory in the Pharmacy.

All thefts or significant losses must be reported to the DEA officials. In any instance that a pharmacy, practitioner, or other DEA registrant authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy, practitioner, or other DEA registrant shall also send a copy to the Board within two (2) weeks of filing with the DEA.

Procedure For Destroying Controlled Substances

Contact the U.S. Department of Justice, 1000 N. Water Street, Room 1010, Milwaukee, WI 53202 or www.deadiversion.usdoj.gov for the proper forms and procedures.

Approved Prescription Drug Products and Code of Federal Regulations

These publications are obtainable from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401.

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Wis. State. Stat. § 450.06(3), requires that a new wholesale distributor license be obtained following a change of ownership. The following chart sets forth when a change of ownership is deemed to have occurred or not occurred. Following the issuance of a new license, that new licensee must also renew that new license at the next required renewal date, regardless of when that new license was issued.

Owner	Transaction	Change in Ownership?
Individual	Sells wholesale distributor to another	Yes
Individual	“Incorporates” him or herself and there are no other shareholders.	No (only a change in <u>business</u> form of owner)
Individual	Incorporates and adds shareholders other than self, or goes into partnership with other(s).	Yes
Partnership	Sells distributor to another	Yes
Partnership	Members of partnership change <u>and</u> dissolves; e.g., individual(s) leaves.	Yes
Partnership	Members of partnership change, but partners vote not to dissolve unanimously or by partnership agreement.	No
Partnership	Partnership decides to incorporate itself.	No (Again, only submit a <u>change in business</u> form, as long as no shareholders added who were not partners before.)
Corporation*	Change in shareholders (including sale of all stock)	No (Corporation owns wholesale distributor—not shareholders.)
Corporation	Sells all assets (as opposed to stock)	Yes (One asset being sold is wholesale distributor; corporation no longer owns it after asset sale.)
Corporation	Becomes a subsidiary or division of another corporation	No (Corporation still owns wholesale distributor, regardless of who owns corporation.)
Corporation	Merges into/or consolidates with another corporation <u>and</u> loses corporate “identity”.	Yes

***Limited Liability Companies created under Ch. 183, Stats., are the same as Corporations for change of ownership.**

If you answered “yes” to any of the above items, **you cannot renew your current license**. You must go the Department website at: www.dsps.wi.gov, choose the appropriate profession, view the application/forms page and follow all application instructions.

If none of the above pertains to your situation, view the Frequently Asked Questions for further information.

Q: We would like to change our DBA name, how do we notify the Board?

A: Please submit a letter to the board indicating that this is a name change only and change of ownership has not occurred. Include your current and new name with your WI license number. You may print a new licensing on our website at <https://online.drl.wi.gov/UserLogin.aspx>, or you may submit a [request Form \(#3082\)](#) and \$10.00 to the Department to have one mailed to you.

Q: We would like to change our address, how do we notify the Board?

A: If this is a postal change only and **no physical move has taken place**, submit a letter to the board indicating that this is a postal change only and no physical change of location has occurred. Include your current /new address with your WI license number. If it is a physical change of location, then a new application must be completed in order to receive a new license number. Applications can be found on the Department website at: www.dsps.wi.gov. Go to the "Application/Forms" link posted under your profession.

Q: We would like to close our facility, how do we notify the Board?

A: For Wholesale Distributors, Drug or Device Manufacturers and Pharmacy (out-of-state only) Please submit a letter to the Board requesting closure. Indicate your facility name license number and reason for closure.

For Pharmacy (In-state) you must file a Pharmacy Closing Affidavit (Form #606) available on the Department website at <http://dsps.wi.gov>, Go to "Application/Forms" link posted under your profession.

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PHARMACY EXAMINING BOARD

APPLICATION FOR WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUG LICENSE

Under Wisconsin law, the Department must deny your application if you are liable for delinquent State Taxes or Child Support (Wis. Stats. § 440.12).

PLEASE TYPE OR PRINT IN INK		<input type="checkbox"/> Your name and address are available to the public. Check box to withhold street address/PO Box number from lists of 10 or more credential holders (Wis. Stat. § 440.14).
Current WI License Number: <input type="text"/> 45	You must choose one of the following Types: <input type="checkbox"/> New Facility <input type="checkbox"/> Change of Ownership <input type="checkbox"/> Change of Location	
Applicant's Name (individual, partnership, association or corporation) <input type="text"/>		
DBA Name (name or title under which business is operated) <input type="text"/>		
Applicant's Telephone Number <input type="text"/> - <input type="text"/> - <input type="text"/>	Business Telephone Number of Wholesale Distributor <input type="text"/> - <input type="text"/> - <input type="text"/>	
FEIN Number of Wholesale Distributor Facility <input type="text"/> - <input type="text"/>	Your Social Security Number or Employer Identification Number must be submitted with your application on this form. If you do not have a Social Security Number, you must complete Form #1051. The Department may not disclose the Social Security Number collected except as authorized by law.	
Distribution Facility Address (number, street, city, state, zip) <input type="text"/>		
Mailing Address (if different) (number, street, city, state, zip) <input type="text"/>		
Name of Contact Person for the Wholesale Distributor Facility applying for the License <input type="text"/>		
Email Address <input type="text"/>		

APPLICATION FEES: Please check applicable box. Make check payable to DSPS and attach to this application.

☐ \$ 74.00 Initial Credential Fee

For Receipting Use Only (45)

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APPLICATION IS NOT COMPLETE UNTIL ALL OF THE FOLLOWING DOCUMENTS HAVE BEEN RECEIVED:

- | | |
|--|--|
| <input type="checkbox"/> Application (Form #2814) and appropriate fee | <input type="checkbox"/> Phar 13.05(4) Surety Bond (Form #2819), Irrevocable Letter of Credit (Form #2824) |
| <input type="checkbox"/> Convictions and Pending Charges (Form #2252) | |
| <input type="checkbox"/> The Authorization for Release of FBI Information (Form #2687) | |
| <input type="checkbox"/> Complete and submit Designated Representative Form (#2812) | |

Note: It may be helpful and may speed up the application review process, if you provide documents regarding your business model and organizational charts for your company. Please submit documentation with your application (**Form #2814**).

SECTION A: (attach additional sheets if necessary)

Indicate below the type of ownership or operation for the applicant's business:

- | | |
|---|---|
| <input type="checkbox"/> Partnership (complete #1 and #1a.) | <input type="checkbox"/> Corporation (complete #2) |
| <input type="checkbox"/> Sole Proprietorship (complete #3) | <input type="checkbox"/> LLC or Other (i.e., members) (complete #4) |

Note: It may be helpful and may speed up the application review process, if you provide documents regarding your business model and organizational charts for your company. Please submit documentation with your application (**Form #2814**).

1. If the type of business is a partnership, name each partner and the name of the partnership:

Name of Partnership:

1a. List below the full names of each partner:

Name

Name

2. If the type of business is a corporation, list below the full name of each corporate officer and director, name of the corporation and the state in which it was incorporated: (attach additional sheets if necessary)

Name of Corporate Officer(s)

Name of Director

Name of Corporation

State Incorporated

3. If the type of business is a sole proprietorship, list below the full name of the sole proprietor and the name of the business entity:

Printed Full Name of Sole Proprietor

Printed Name of Business Entity

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4. If the type of business is a LLC or other entity, list below the full name of each member and the name of the business entity: (attach additional sheets if necessary)

Name of Business Entity

Member(s)

List below all current licenses and permits issued to the facility applying for the license by any other state that authorizes the applicant to purchase or possess prescription drugs: (attach additional sheets if necessary)

State	Expiration Date	Type of License or Permit
<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>
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<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>

Name and Address of Designated Responsible Representative for the Distribution of Prescription Drugs: The Designated Representative named below must complete and return the Designated Representative (**Form #2812**) and attach with this application.

Printed Full Name of Designated Representative

Address (number, street, city, state, zip)

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SECTION B: Applicant read and sign below.

I swear or affirm to the truthfulness of each item in the attached Designated Representative (**Form #2812**), submitted with this application.

Signature of Applicant

Title

Printed Name

 / /

Date

SECTION C: Applicant read and sign below.

I swear or affirm that each facility used for the wholesale distribution of prescription drugs has been inspected in the 3-year period immediately preceding the date of this application.

If you have not been inspected in the 3-year period immediately preceding the date of this application, your application will be denied and the application fee will not be returned. Once the required inspection is obtained a new application will need to be filed and a new application fee paid. You may not conduct business in Wisconsin while awaiting licensure.

Check below the type of Inspection you had.

☐ **A State Board of Pharmacy**

Note: Please have Designated Representative submit electronic fingerprints. See instructions on (**Forms #2813 and #2812**).

List State:

Date Last Inspected: / /

☐ **NABP (VAWD)**

Note: If VAWD is used, you will not need the Designated Representative to submit electronic fingerprints.

VAWD Unique Identifier:

Period of Accreditation:

From: / / To: / /

☐ **Other Accrediting Body**

Note: Inspections or accreditations from agencies other than a State Board of Pharmacy or VAWD will be reviewed by the Pharmacy Examining Board's Liaison.

Date Last Inspected:

 / /

Signature of Applicant

Title

Printed Name

 / /

Date

Wisconsin Department of Safety and Professional Services

SECTION D: Applicant read and sign below.

Phar 13.05(4) Surety bond, irrevocable letter of credit. The applicant shall supply a surety bond or irrevocable letter of credit in the amount of \$5,000.00, which is issued by a company authorized to do business in the State of Wisconsin. The form of the bond or letter of credit shall be approved by the Department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a Wholesale Distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this subsection more than one year after the date on which the applicant's Wholesale Distributor license expires. **SURPLUS LINE** – Insurers **are not** authorized to do surety business in Wisconsin

Check one of the following.

☐ \$5,000 Bond

If the applicant chooses to obtain the \$5,000 surety bond, please complete and return the Bond of Prescription Drug Wholesale Distributor (**Form # 2819**).

☐ \$5,000 Irrevocable Letter of Credit (**enclosed with this application**)

SECTION E: Applicant answer the following questions:

1. Is applicant now or has applicant ever been credentialed by a Federal Agency? **If yes, complete below:**

☐ Yes ☐ No

Agency:

Registration Number:

Expiration Date:

 / /

2. Is applicant a Manufacturer of prescription drugs? **If yes, indicate below.**

☐ Yes ☐ No

Food and Drug Administration Registration Number:

Expiration Date:

 / /

3. Is applicant a Manufacturer and/or repackager of controlled substances? **If yes, indicate below:**

☐ Yes ☐ No

Food and Drug Administration Registration Number:

Expiration Date:

 / /

4. Has the applicant previously been licensed by the Wisconsin Pharmacy Examining Board?

☐ Yes ☐ No

If yes, give name, license number and location.

Is this facility closed? ☐ Yes ☐ No

5. Has the applicant ever been convicted of a felony or misdemeanor? **If yes, attach a sheet providing details about the pending charge, copy of the court documents and status of the charge and complete Convictions and Pending Charges (Form #2252)?**

☐ Yes ☐ No

6. Has the applicant had their Pharmacists, Pharmacy, Manufacturer, or Distributor license suspended, revoked, or reprimanded in this or any other state? **If yes, attach a sheet providing details about the action, including the name of the credentialing agency and date of action**

☐ Yes ☐ No

7. Does the applicant have a Pharmacy, Pharmacist, Manufacturer, or Distributor license now subject to disciplinary proceedings in this or any other state? **If yes, attach a sheet providing details about pending action, including the name of the agency and status of action.**

☐ Yes ☐ No

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CONTINUING DUTY OF DISCLOSURE:

I declare under penalty of law that I am (check one):

- ☐ A citizen or national of the United States, or
- ☐ A qualified alien or nonimmigrant lawfully present in the United States who is eligible to receive this professional license or credential as defined in the Personal Responsibility and Work Opportunities Reconciliation Act of 1996, as codified in 8 U.S.C. §1601 et. Seq. (PRWORA). For questions concerning PRWORA status, please contact the U.S. Citizenship and Immigration Services in the Department of Homeland Security at 1-800-375-5283 or online at <http://www.uscis.gov>.

Should my legal status change during the application process or after a credential is granted, I understand that I must report this change to the Wisconsin Department of Safety and Professional Services immediately.

AFFIDAVIT OF APPLICANT:

The undersigned, having been duly sworn on oath, states that the facts and statements herein contained are true and correct based upon personal knowledge of the undersigned. By signing below, I am signifying that I have read the above statements (Continuing Duty of Disclosure and Affidavit of Applicant) and understand the obligation I have as an applicant or credential-holder should information I've provided to the Department of Safety and Professional Services change

Signature of Applicant

Title

Printed Name

 / /

Date